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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	U022 1020.1	1163

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,657	WOOLEY ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/07 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1,2,5-9,12-15,19 and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder (USPN 5,565,189 hereafter '189) in view of Raad et al (USPN 6,267,979 hereafter '979). The claims are drawn to a method of inhibiting

proliferation of a bacterial population if a skin injury by applying a topical formulation comprising a synergistic cooperation between the an antibacterial agent and a chelating agent.

5. The '189 patent discloses a method of treating infected wounds including applying a composition to the injury comprising a biocide (hydroxyquinoline) and a chelating agent (sodium EDTA) (example 1). The artisan of ordinary skill would be able to identify the microbial infection, apply the composition while making appropriate modifications to the components in order to maximize the effectiveness of the treatment. These mental steps and preparations would be apart of any treatment regimen along with optimizing the concentrations of the components in order to maximize the microbial treating features of the invention. The reference is silent to a synergistic relationship between the chelator and the biocide, however this relationship is well known in the art.

6. The '979 patent discloses a disinfecting composition comprising a synergistic combination of chelating agents and antimicrobial agents (abstract, example 5). The chelators include various EDTA derivatives along with Diethylene triamine pentaacetic acid (DPTA), and triethylene tetramine dihydrochloride (TRIEN) while the antibacterial agents include minocycline, oxytetracycline, tetracycline, gentamicin and erythromycin (example 5). The EDTA is present in concentrations from 0.1 –10,000 ppm (col. 4, lin. 35-40). More specifically in one embodiment of the invention the EDTA is present in a concentration of 30 g/L, which is approximately 102 mM (example 4). It is the position of the Examiner that the concentration of chelators is merely an optimizable limitation as long as synergy is maintained. In each embodiment of the '797 patent synergy is maintained. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

7. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

8. Regarding the specific bacterial infections treated by the invention, it is the position of the Examiner that these limitations would be inherent to the antibacterial agents chosen. Since the limitations regarding specific biocidal agents have been met, the corresponding bacterial infections would also be treated by the combination of the prior art.

9. With these things in min it would have been obvious to include the synergistic combination of the '979 patent into the method of the '189 patent in order to improve the biocidal properties of the wound cleanser of prior art. One or ordinary skill would have been motivated to combine the synergistic combination into the method since both patents solve the same problem of treating bacterial infections. It would have been obvious to combine the teachings and suggestions of the prior art with an expected result of a method of treating surface bacterial infections.

10. Claims 1 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mulder (USPN 5,565,189 hereafter '189) and Raad et al (USPN

6,267,979 hereafter '979) in view of Cuny et al (USPN 6,207,679 hereafter '679). The claims are drawn to a method of treating specific injuries.

11. As discussed above the combination of the '189 and '979 patent provide a method of treating injuries by applying a combination of chelators and biocides in a synergistic relationship. The combination is silent to the specific types of injuries or dosage from, however all topical liquid formulation are disclosed by the '189 patent. Specific injuries would be obvious to treat to the artisan of ordinary skill since the general problem of eliminating a bacterial infection at a wound site is disclosed in the prior art. Specific injuries are well within the level of skill in the art prior art as seen in the '679 patent.

12. The '679 patent teaches the use of antimicrobial agents in the treatment of infections (bacterial/fungal) in wounds such as burns, ulcers, scrapes and bruises (abstract, col. 34, lin. 40-55). The formulations can be used to sterilize medical devices or treat bacterial or fungal infections on internal mucosa, both orally and vaginally (*Ibid.*). Formulations include solutions, elixirs and mouthwashes (col. 38, lin. 46-57). The formulation is effective against both Gram-positive and negative bacterial genus such as *Pseudomonas* and *Staphylococcus* (col. 32, lin. 17-39). The formulation comprises various antimicrobial agents such as penicillins, amino glycosides, and cephalosporins along with carriers and chelators such as EDTA (col. 36, lin. 7-16; col. 38, lin. 19-20). A skilled artisan would have been motivated by these teachings to administer the formulation of the '189 and '979 combination to the skin for wound treatment as taught by '679.

13. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of '679 to combine biocidal compounds such as those found in both '679

and '484 in order to treat Gram-positive or negative bacterial infections. The '189/'979 combination teaches the importance of a synergistic relationship between the chelator and the biocide, while the '679 teaches the varying methods of application. The minimum inhibitory concentration (MIC) for each compound would be known by one of ordinary skill in the art as shown in the '679 patent. It would have been obvious to follow the suggestions of '189/979 combination in order to topically treat bacterial infections with an expected result of a method of treating infected wounds.

14. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulder (USPN 5,565,189 hereafter '189) and Raad et al (USPN 6,267,979 hereafter '979) in view of Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to a method of treating a bacterial infection with specific biocides.

15. As discussed above the '189/'979 combination discloses a synergistic combination comprising chelators and biocides useful in antibacterial methods. The reference is however silent to eh specific agents recited in the claims, however the inclusion of these agents is well within the level of skill in the art.

16. The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. A skilled artisan would be motivated to include the antibiotics of the '151 patent in order to treat a wider range of bacterial infections.

17. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '151 patent into the combination of '189/'979 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with en expected result of a topical wound healing formulation capable of treating a wider range of infections.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3,12-15,18-21,25-29,43 and 44 of copending Application No. 10/739,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of treating a wound with a composition comprising chelators and antibacterial agents. The claims recite the same chelators and antibacterial agents. Although the claims of the '841

patent include further components, the claims of the instant claims are open to further components that do not change the material properties of the invention. For these reasons the claims of the instant claims would act as obviating art over the '841 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

20. Applicant's arguments with respect to claims 1,2,5-15,18-22,56-62 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER